Study Title: Adaptation of the Friendship Bench Intervention for HIV-infected Perinatal Women in Lilongwe

NCT Number: NCT04143009

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This consent form should be signed only between 24 Nov 20 and 24 Sept 21
Approved by NHSRC, Malawi on 24 Nov 20

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants – Arm 2: Enhanced Friendship Bench (EFB)

Consent Form Version Date: version 4.0 dated September 09, 2020
IRB Study #: 19-1689
NHSRC #: 19/08/2379
Title of Study: UNCPM 21910 - Phase 2 - Adaptation of the Friendship Bench mental health intervention for HIV-infected perinatal women in Lilongwe.

Principal Investigator: Brian Pence, PhD
Principal Investigator Department: Epidemiology Operations
Principal Investigator Phone number: +1 919-966-7446
Principal Investigator Email Address: bpence@unc.edu
Funding Source and/or Sponsor: National Institute of Mental Health (NIMH)

Study Contact Telephone Number: Steve Mphonda; 0999 272 759
Study Contact Email: smphonda@unclilongwe.org

CONCISE SUMMARY
The purpose of this research study is to assess the feasibility, fidelity, and acceptability of the Enhanced Friendship Bench intervention to improve perinatal depression and engagement in HIV care. Participants will include 184 (92 HIV positive pregnant women and their babies across 5 sites. The study will last about 18 months.

Study procedures will include 4 individual prenatal counseling session, 2 group postnatal counseling sessions, 1 social support person session and HIV viral load measurement by finger-prick. During these sessions, participants will be asked to identify barriers to engagement in HIV care, identify a feasible solution, agree on an action plan to address the barriers and identify a support person to bring with them to the sessions.

Redness, pain, swelling, bruising, or an infection may occur where your blood is drawn. This is the same risk as in any routine blood draw. There is also a potential psychological risk of emotional distress and embarrassment due to the sensitive nature of some of the questions. You may choose not to answer any questions if you are uncomfortable with answering them. You may experience improvements in the symptoms of perinatal depression which may have benefits to your infant and at a societal level the results of this study will improve our understanding of how an adapted and enhanced counseling intervention may improve perinatal depression (PND) and engagement in HIV care.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any

reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to assess the feasibility, fidelity, and acceptability of the Enhanced Friendship Bench intervention to improve perinatal depression (PND) and engagement in HIV care.

You are asked to be in this study because: 1) you have screened positive for depression 2) you are at least 18 years of age, 3) you are HIV positive and pregnant, 4) you have had recent feelings of sadness or worry, 5) you are starting to take or are taking anti-HIV medications (also known as antiretroviral treatment, or "ART").

How many people will take part in this study?
If you decide to be in this study, you will be one of approximately 92 women and their babies in this research study.

How long will your part in this study last?
Your participation in the study could last up to 15 months, and include up to 2 study visits to this clinic and up to 7 counseling sessions over that time.

What will happen if you take part in the study?
If you decide to be in this study, you will complete an interview today and another interview about six months after your baby is born. At this second interview, we will also measure your baby's height and weight and collect information about your baby's health development, and HIV status from you and your baby's medical records. At the second visit we will prick your finger to measure your HIV viral load. We will also take a short video recording of you and your infant playing with a new toy.

This second interview may happen in person or by phone. The height, weight, and viral load measurement will happen in person.

After today's interview, you will be asked to participate in approximately 4 individual prenatal counseling session and approximately 2 group postnatal counseling sessions. You will also have

the opportunity to bring a friend or family member to a session if you wish, and the opportunity to have the counselor visit you at home if you wish.

Prenatal counseling sessions: Each session will last 30-45 minutes. During these sessions, the study counsellors will work with you to identify problem you are having, identify a feasible solution, and agree on an action plan to address the problem.

Postnatal group counseling sessions: Group counseling sessions will be optional. Each session will be facilitated by a psychosocial counselor. All sessions will include 5-8 women and will last ~60 minutes. During these sessions, participants will be invited to share their experiences and support each other.

Strengthening social support sessions: For this optional session, you will be invited to include a person of your choice who can be a support to you in managing both your HIV and/or depression, such as a partner, friend, or companion. During these sessions, you, your support person, and the counselor will discuss ways your support person can be a support to you. You do not have to include a support person to this session if you do not want to.

Home visits: Home visits will be optional. The counselor will visit you at home. Home visits will start in the third trimester and continue through up to 6 months postpartum. At these visits, your counselor will deliver your HIV medications and conduct a counseling session, if there is enough privacy to do so. You and the counselor can agree on a story about who the counselor is if needed to protect your privacy (your aunt from another village, for example). You do not have to have home visits if you do not want to.

Counseling sessions may be recorded. These recordings will not be linked to your name and will not be shared with anyone outside the research team. If you do not want your counseling sessions recorded, you can still participate in the study.

All counseling sessions may happen in person or by phone.

What are the possible benefits from being in this study?

By participating in counseling, your feelings of sadness or worry may improve and at a societal level the results of this study will improve our understanding of how an adapted and enhanced counseling intervention may improve Perinatal depression (PND) and engagement in HIV care.

What are the possible risks or discomforts involved in being in this study?

The risks of taking part in the interview are small, if any. Some questions could make you feel uncomfortable or embarrassed. You may choose not to answer any question for any reason and you can leave the interview at any time. Redness, pain, swelling, bruising, or an infection may occur where your blood is drawn. This is the same risk as in any routine blood draw

Another possible risk is that in the optional group sessions, other members may not keep all information private and confidential. All participants are asked to respect the privacy of other group members in each discussion and ask that group members not disclose anything said in the group discussion.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. If you do not participate in this study, you will continue to receive your regular medical care.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Every effort will be taken to protect your identity as a participant in this study. You will be assigned a participant identification number, and that number will be used in the database and on the study folders and forms instead of any identifying information. The only locations where the participant identification number could be linked to information that identifies you will be in an electronic study ID linkage file, which will be stored on a secure and password-protected computer.

No participants will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when the law requires the disclosure of such records, including personal information. In some cases, your information in this research study could be reviewed by the University of North Carolina at Chapel Hill Institutional Review Board (UNC-CH IRB) and the National Health Sciences Research Committee (NHSRC), representatives of the University, research sponsors, study staff, study monitors, or government agencies for purposes such as quality control or safety.

If you agree, we will use a digital tape recorder to record our conversations with you. All audio files will be stored on a secured computer server that can only be accessed by members of the study team. This audio recording will be transcribed so that we have a record of the conversation. The transcription will be done by a member of our research team and/or an outside professional transcriber. We will destroy the audio recording of this discussion one year after we complete the transcription process. If you do not want your counseling sessions recorded, you can still participate in the study.

Check the line that best matches your choice:
_____ OK to record me during the study
_____ Not OK to record me during the study

What is a Certificate of Confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled

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abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study. Finally, we may share limited information with health care staff or other officials if we have a concern about your safety or the safety of someone else.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but neither the University of North Carolina at Chapel Hill nor the sponsor, National Institute of Mental Health (NIMH) has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be receiving 7,000 kwacha for today's interview and also for the second interview 6 months after your baby's birth. Your baby will also receive a small toy at the 6 month interview. You will also receive 3,500 kwacha for each of the seven counseling sessions you attend before and after your baby is born.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institute of Mental Health (NIMH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Chairman, Dr. Matias

Joshua at +265 999 39 79 13 OR the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Principal Investigator: Brian Pence, PhD

Participant's Agreement:
If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name, make your mark or place your thumbprint** in the signature area at the bottom of this page.

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

Participant Name (print)	Participant Signature	Date
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** below.

Mark or Thumbprint of participant if unable to sign

Participant Mark or Thumbprint

_____		_____
Participant Name (print)		Date

Participant Name and Date Written By.....on.....

_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

_____	_____	_____
Impartial Witness Name (print)	Impartial Witness Signature	Date